

REMARKS

Claims 1-14 are now pending.

The Applicants indeed thank the Examiner for entering the amendments and the 1.132 declaration of physical fact, i.e., the hygroscopicity, *per se*, of the calcium salt in relation to the sodium salt of the same compound.

Summary

The Applicants respectfully highlight to the Examiner that the optically active crystalline calcium salt of fluvastatin described and claimed herein is, *in fact*, remarkably and unexpectedly less hygroscopic than the sodium salt, i.e., 2.8% gain at 84% relative humidity (RH) vs. 26.0% gain at 84% RH, respectively.¹ Applicants submitted the Declaration of Ada Skorodinsky according to 37 C.F.R. §1.132 on May 30, 2008 that unequivocally demonstrated the unexpected results of the present invention in a direct hygroscopic analysis of fluvastatin sodium versus fluvastatin calcium. The Examiner's response to said Declaration was "[t]here is no data to explain the unexpected results". July 9, 2008 Office Action, Page 8.

The Examiner rejects the now pending claims drawn to the optically active crystalline calcium salt of fluvastatin as obvious under the current authoritative judicial interpretation of the statutory requirement of 35 USC §103(a). The Examiner particularly points clearly to the absence of "data to explain the unexpected results", while indicating that the rejection will be withdrawn if the unexpected results are explained.

The sodium and calcium salts of fluvastatin were subjected to a head to head hygroscopic test, which measured the amount of water, as water vapor, that each salt absorbed from the atmosphere. The sodium salt was found to absorb almost 10 times the amount of moisture from the atmosphere as the calcium salt. The disparity in relative hygroscopicity would not have been obvious to one of skill in the art at the time of the invention when presented with a mere

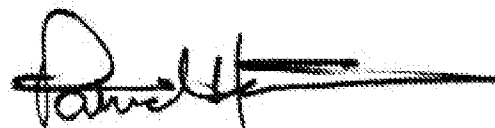
¹ The Applicants specifically teach in the written description of the present disclosure *specifically* how to manufacture the optically active crystal and ascertain the identity of the species, *per se*. The subject matter of claim 8, for example, is limited to an optically active crystalline calcium salt of fluvastatin which exhibits a powder X-ray diffraction pattern with maxima at 2θ values of 5.3, 11.8, 13.9, 17.5, 19.1, 22.0 and 23.1 and which has a melting point of about 220°C. See, e.g., Applicant's disclosure at Page 5.

“shopping list” of possible salts. As one of skill in the art is fully aware, a salt form that is less hygroscopic will most likely have a longer shelf life and is usually easier to formulate.

The Applicants respectfully remind the Examiner, however, that unexpected *results, per se*, are indicia of non-obviousness. Nowhere does the statute, or any authoritative interpretation thereof, require data to *explain* the unexpected results. **Superiority of an important property shared with the prior art can be compelling evidence of nonobviousness.** The physical property presented as fact, i.e., the substantially reduced hygroscopicity of the claimed subject matter compared to the closest prior art,² is an established fact, *per se*, on the record of this case. The Applicants respectfully emphasize to the Examiner that the inherent advantageous property, presented as fact, is critical indicia in this case. The Applicants respectfully highlight to the Examiner that the optically active crystalline calcium salt of fluvastatin described and claimed herein is, *in fact*, remarkably and unexpectedly less hygroscopic than the sodium salt, i.e., the compound exhibits about 1/10 the hygroscopicity. The specification need not disclose proportions or values as critical for applicants to present evidence showing the proportions or values to be critical. See, e.g., MPEP 716.02(f). The reason for requiring evidence in declaration or affidavit form is to obtain the assurances that any statements or representations made are correct, as provided by 35 USC 25 and 18 USC 1001.

The Applicants respectfully submit that claims 1-14 are in condition for allowance. Early action toward this end is courteously solicited. The Examiner is kindly encouraged to telephone the undersigned in order to expedite any detail of the prosecution. The Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 02-2556.

Respectfully submitted,



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October 8, 2008

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² An affidavit or declaration under 37 CFR 1.132 must only compare the claimed subject matter with the closest prior art. MPEP 716.02(e).

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